

K071722

510(k) Summary
for the E.M.S. ELECTRO MEDICAL SYSTEMS SA
Deep Blue[®]

1. SPONSOR

EMS ELECTRO MEDICAL SYSTEMS SA
Ch. de la Vuarpillière 31
CH - 1260 Nyon
Switzerland

AUG 10 2007

Contact Person: Sandra Baumgartner
Telephone: 022 994 47 00

Date Prepared: June 22, 2007

2. DEVICE NAME

Proprietary Name: Deep Blue[®]
Common/Usual Name: dental curing light
Classification Name: ultraviolet activator for polymerization

3. PREDICATE DEVICES

- Mini L.E.D. (K032465), SATELEC
- LED Turbo PEN (K041303), Apoza Enterprise Co.

4. INTENDED USE

The Deep Blue[®] is a dental curing light that is intended for use in dental procedures requiring the photopolymerization of materials.

5. DEVICE DESCRIPTION

The Deep Blue[®] consists of a detachable handpiece that contains the LED (light emitting diode) light source, microprocessor control system, a light guide that directs light to the treatment area on the patient, and a connector for connection of the device to a power source. Two versions of the device will be marketed in the U.S., the Doris I and Doris II. The Doris I and Doris II configurations differ in the power source. The

Doris I configuration is powered by a connection to a commercially available EMS Electro Medical Systems ultrasonic scaler. The Doris II configuration is powered by an electrical connection to a dental operative unit. The function of the connected ultrasonic scaler or the dental operative unit is limited to providing power to the handpiece.

6. TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE

Both the proposed Deep Blue[®] and the predicate curing lights are designed for the photopolymerization of dental resins (see table on following page). The operational principles of the proposed and predicate devices are identical. The light source is an LED in a handpiece with a light guide inserted. The operator orients the tip of the light guide relative to the material being photopolymerized and activates the curing light using the foot switch to initiate a treatment session.

Differences between the proposed Deep Blue[®] and the predicate curing lights are limited to design differences, light output power, and available operational modes. Performance testing has been conducted that confirms that the Deep Blue[®] is able to cure resin within the specified timeframe without causing thermal damage to the tissue.

The similarities in intended use, technical specifications, and functional performance between the Deep Blue[®], Mini LED, and LED Turbo PEN curing lights leads to a conclusion of substantial equivalence between the proposed and predicate devices.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

E.M.S. Electro Medical Systems SA
C/O Cynthia J. M. Nolte, Ph.D., RAC
Senior Regulatory Consultant
Medical Device Consultants, Incorporated
49 Plain Street
North Attleboro, Massachusetts 02760

AUG 10 2007

Re: K071722

Trade/Device Name: Deep Blue®
Regulation Number: 21 CFR 872.6070
Regulation Name: Ultraviolet Activator for Polymerization
Regulatory Class: II
Product Code: EBZ
Dated: June 22, 2007
Received: June 22, 2007

Dear Dr. Nolte:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.


If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read 'Chiu Lin', with a stylized flourish at the end.

Chiu Lin, Ph.D.

Director

Division of Anesthesiology, General Hospital,

Infection Control and Dental Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K071722

Device Name: Deep Blue®

Indications for Use:

The Deep Blue® is a dental curing light that is intended for use in dental procedures requiring the photopolymerization of materials.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)

Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K071722